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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,202	10/10/2003	Avraham Shekalin	08875.0005-02000	1247
21127	7590	09/23/2004	EXAMINER	
KUDIRKA & JOBSE, LLP ONE STATE STREET SUITE 800 BOSTON, MA 02109			MICHENER, JENNIFER KOLB	
			ART UNIT	PAPER NUMBER
			1762	
DATE MAILED: 09/23/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/682,202	Applicant(s) SHEKALIM ET AL.	
	Examiner Jennifer K. Michener	Art Unit 1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 July 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 37-43 and 45-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37-43 and 45-81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Double Patenting*

1. The rejection of claims 37-43 and 45-52 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-15 of prior U.S. Patent No. 6,645,547 has been withdrawn based on Applicant's amendments.

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 37-43, 45-61, 63-65, 67-75, and 77-81 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,645,547. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pending claims are merely broader embodiments of the patented claims.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 62, 66, and 76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation of application at an "angle relative" appears to be new matter. Examiner is unable to find, in the originally-filed disclosure, reference to such an angled application.

6. Claims 54, 56-59, 73-74, and 76-81 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for optically scanning a stent to produce output indicative of the different types of surfaces to trigger activation of a coating applicator, does not reasonably provide enablement for the broad steps of determining whether or not the coating applicator is aligned with only the surface of the stent to activate the coating applicator. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The limitations of these claims are broader than the enabling disclosure. The disclosure's scope of enablement provides only optical scanning as a means of "determining" alignment to produce output

which triggers a response from the applicator. The broad claiming of “determining” and “activating”, without the use of optical scanning and production of output which triggers activation of a coating applicator, is open to various methods not enabled by the specification. The claims as written are broad enough to require only a human eye to direct a human hand to apply the coating or to require a sensing mechanism to “feel” its way along the struts of a stent to apply coatings. None of these methods fall within the scope of the instant invention and the specification does not enable a person skilled in the art to use the invention commensurate in scope with these claims.

### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 37-43, 45-51, 53-55, 57-69, and 71-81 are rejected under 35 U.S.C. 102(e) as being anticipated by Castro (6,395,326).

Castro teaches applying a patterned coating to a stent. Castro teaches a feedback system including a video camera for capturing an image which feeds image data to the dispenser, motion control system, and/or holding device to direct deposition of the composition (col. 5, lines 1-10). Castro teaches that the lens contains a set of optics

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(col. 10, line 18) and that the vision software can determine the difference between multiple images, such as individual stent struts, patterns, and position (col. 10, lines 35 and 44). Castro teaches that the coating method of his invention may be used to follow the struts of a stent to avoid webbing between the struts (col. 2, line 57) or to deposit coatings, such as therapeutic agents, only intermittently.

Figures 2A, 4, and 6 show a stent mounted on a mandrel structure for coating.

Therefore, Castro's optical device scans the stent and can distinguish between struts and non-strut areas and between cavities and non-cavity areas to deposit coating selectively, depending on the embodiment, to struts or to cavities within the struts without applying to the mandrel.

Figures 2B and 6B indicate rotation of the stent along a rotation (36) axis, which is perpendicular to the applicator.

The elongate holder of the Figures supports the stent from the inside, which supports the device in at least two regions.

Castro teaches pressure drop systems for ejecting the coating material through the deposition nozzles (col. 9).

The drop ejector is part of a dispenser assembly, which acts as a sub-housing, that includes at least one nozzle connected to a reservoir. All housings are inherently "removable".

A second composition may be applied concurrent with or subsequent to the deposition of the first composition of Castro. The two compositions may be deposited in an overlapping manner or in a manner so as not to overlap one another (col. 19). Castro allows for a plurality of nozzles (col. 9, line 15).

Castro teaches, in some embodiments, coating the entire stent.

Castro teaches moving the applicator in the x, y, and z directions, controlled by a CPU (Figures; col. 10, lines 6 and 12). When moving in the y-direction, Castro would vary the space between the nozzle and the object.

The dispenser has a motion control system which is capable of terminating, or "deactivating", the motion of the dispenser from a termination signal from the CPU. Additionally, as outlined above, the camera can determine a position, which would indicate relative motion, which is one variable used in changing operation parameters of the coating device.

Castro's figures teach deposition at an angle.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Castro.

Castro teaches that which is disclosed above but fails to specify that the above operations are performed in a housing.

However it is Examiner's position that it would have been obvious to one of ordinary skill in the art of coating implantable medical devices to enclose Castro's coating operation within a housing in order to avoid contamination of the coated implantable device.

***Response to Arguments***

11. Applicant's arguments with respect to claims 37-43 and 45-54 have been considered but are moot in view of the new ground(s) of rejection and the newly-submitted claims.

***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hansen is cited for teaching the use of alligator clips to hold the ends of a stent while spray-coating. From the Figure, it appears that the coating applicator is directed to the mounted stent. Since the surfaces are not predominantly in



contact with other surfaces, the coating applicator would be "determined" by a user to be aligned with only the surface of the stent and the user would inherently "activate" the coating applicator at such a time.

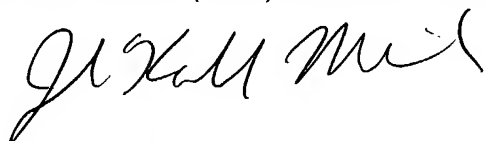
13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer K Michener whose telephone number is (571) 272-1424. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 571-272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in cursive script, appearing to read "J Kolb Mich", is positioned above the typed name.

Jennifer Kolb Michener  
Patent Examiner  
Art Unit 1762  
September 20, 2004